

04-7984
P.C. 8400142



July 12, 2004

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Re: Written Response to Mandatory Guidelines for Federal Workplace Drug Testing Programs, FR Doc 04-7984

Dear Dr. Vogl

Below is NOTA's response to your proposed revision to the Mandatory Guidelines. We appreciate the number of opportunities you have provided us to share information with you. Some of our members are submitting their own comments.

The use of on-site drug testing products enhances drug-free workplace programs and permits cost-effective and faster drug testing methods while preserving the integrity of the programs. We are glad that the SAMHSA Mandatory Guidelines will include these new and improved technologies.

Comments

1. The Drug Testing Advisory Board (DTAB) should include representatives from the manufacturers of the products that SAMHSA proposes to regulate. The manufacturers know their products the best and it will encourage the exchange of accurate information.
2. SAMHSA's current approach will significantly increase the costs of drug testing without improving the overall accuracy and effectiveness of the program. The use of laboratory-oriented oversight and inspection requirements for on-site testing products is not needed. No detailed knowledge of biology and chemistry is needed to administer the tests or to ascertain if it is positive or negative. Neither laboratory apparatus nor expertise in analysis is necessary to perform the tests. All of the chemistry and the expertise to make the test work have been built into the test device. A person performing one of these tests need not be versed in the biochemical detail and scientific basis of the test any more than a person using an instant camera needs to be versed in the intricacies of photography and film developing in order to take and have instant photographs.

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As SAMHSA has said:

Non-instrumented POCT for urine testing have been subjected to evaluations by investigators independent of the manufacturers and found to perform similar to that of the instrumented immunoassay tests in certified laboratories. These tests were conducted on both spiked and donor specimens with and without drug analytes. Little difference in the performance of these devices was observed between tests conducted by laboratory technicians and laymen who had been trained in the proper procedures for conducting and reading the tests. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Federal Register 19673, 19677 (April 13, 2004).

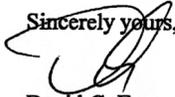
This means that:

1. On-site drug screening tests are technically equivalent to laboratory drug screening tests.
2. Non-laboratorians can perform and correctly interpret on-site drug screening tests.

The manufacturers, DATIA, and the users of on-site tests are submitting detailed comments. We have no wish to be redundant. We have submitted comments in the past on the previous drafts and we reassert those comments that will be still appropriate. We urge you to make the use of these tests as easy and cost effective as you can

We look forward to working with you toward our common goals.

Sincerely yours,



David G. Evans, Esq.
Executive Director